

# **Immunization Program Integrity Being Your Best!**

**Indiana Immunization Conference 2008**  
**ISDH Immunization Program**

# Learning Objectives

At the end of this session, attendees will:

- State three hallmark characteristics of practice integrity
- State three primary provider responsibilities
- Identify three potential consequences of Vaccines for Children (VFC) policy violations



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## Thousands get revaccinated after shots spoil

Poor refrigeration causes hundreds of thousands doses to go bad, CDC says

“By CDC estimates, hundreds of thousands of doses of vaccines...are thrown out each year because of poor refrigeration at clinics, hospitals and doctors' offices.” <http://www.msnbc.msn.com/id/22100133/>



Indiana State  
Department of Health

# Sioux City, Iowa

- More than 1,000 families were notified that they needed to get their children revaccinated
- State officials found that the refrigerator at the clinic where the shots were administered repeatedly dropped below freezing over a 17-month period

**"We just didn't notice it."**

**Dr. Ray Sturdevant**

# There are more!

- Minnesota
  - 8,600 patients had to be revaccinated
  - Most were children
  - Refrigerator was not kept at the proper temperature
  - Gaps in documentation
- Oregon
  - 500 children and adults revaccinated
- Florida
  - 250 children had to be revaccinated
- New Mexico 2007: loss of \$4 million
- Colorado birthing hospital
  - Hepatitis B kept at freezing temperatures
  - 4,300 infants vaccinated with compromised vaccine

# Why “Program Integrity” ?

Storage and handling errors cost the VFC program about \$20 million per year, and most is due to improper refrigeration.

And how many programs are compromised by mishandling and other errors?

- Vaccines given improperly
- Vaccine given to ineligible persons
- Vaccine needlessly expiring in storage units

# What is “Program Integrity” ?

- Best storage and handling practices
- Using VFC vaccine legally and appropriately
- Professional best practices



# Program Integrity

## All Providers

- Utilizing current best immunization practices.
- Seeking continuing education on vaccines and CDC/ACIP recommendations
- Minimal to no vaccine wastage

## VFC Providers

- Maintaining current knowledge base of VFC policies
- Compliance with VFC & ISDH policies

# Program Integrity

## Components

- Education
- Compliance
- Accountability
- Best Clinical Practices

# Implementation

- **Education**

- All providers

- Maintain current knowledge
      - CDC/ACIP recommendations
      - Professional standards

- VFC

- Provider enrollment training
    - AFIX/VFC site visits
    - Seminars and newsletters

# Elements of Education

- Vaccine storage equipment
- Proper storage and handling of vaccine
- 6 Rights of medication administration
- Documentation/ standard operating procedures (S O Ps)
- Adverse event/medication error reporting

# Vaccine Storage Equipment

- Minimum size requirements for refrigerator and freezer
- Emergency back-up plan
  - Generator
  - Alarm system
  - Supplies and staff to move vaccine
  - Work the plan
- Certified calibrated thermometers

# Proper Storage & Handling

- Know specific vaccine and diluent storage requirements
- Follow reconstitution time guidelines
- Attend trainings and request refresher course with new staff
- Never assume

# 6 Rights of Vaccine Administration

- Right patient
  - VFC eligibility screening
- Right medication
  - Check your vials
- Right time
  - Check the schedules
- Right dose
  - Pediatric vs. adult vaccine
- Right route
  - IM, subcutaneous, intranasal, oral
- Right site
  - Based on age, muscle development
  - NO GLUTEAL

# Documentation

- Federal law requirements set forth in the National Childhood Vaccine Injury Act of 1986
- Specifies what must be included in patient's permanent medical record
- Vaccine information statement (VIS) must be given prior to any vaccination
  - Most current version
  - Must be documented



# Adverse Event & Medication Error Reporting

- Vaccine Adverse Event Reporting System
  - VAERS
    - The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:
      - Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine
      - Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination
    - [vaers.hhs.gov](http://vaers.hhs.gov)
- Medication Error reporting
  - Institute of Safe Medication Practices
  - [www.ismp.org/](http://www.ismp.org/)

# Quality Measures

- **All providers**
  - Immunization rates
  - HEDIS rates
  - CHIRP data
  - No wasted vaccine

# Quality Measures

- **VFC Providers**
  - **Site visit assessment**
    - Site visit questionnaire
    - Assesses compliance with VFC program requirements
  - **AFIX process**
    - **Assessment**
      - Current immunization practices, immunization rates
    - **Feedback**
      - Results of assessment given to provider, strategies for improvement
    - **Incentives**
      - Reward and recognize performance improvement
    - **eXchange**
      - Of healthcare information and resources for improvement

# **Provider Accountability**

Striving for Compliance,  
Avoiding Corrective Action

# AFIX and Site visits

## Evaluation of provider practices

- May result in the following:
  - Compliance with best practices:
    - recognition and/or reward
  - Non-compliance or poor practices:
    - Educational referral
    - VFC Order Hold
    - Identification of Fraud and/or Abuse
    - Reimbursement to the VFC Program
    - Referral to outside agencies for punitive action
    - Termination from VFC Program

# Educational Referral

- On-site education (during site visit assessment) for immediate correction
- May refer to health educator for additional training requirement
- Voluntary education also available
  - Contact your regional health educator
  - No cost, can be customized for your needs, schedule for your convenience

# VFC Order Hold

- Non-compliance may result in VFC order being placed on hold
- Based on site visit results or report of possible vaccine mismanagement
- Reinstatement of VFC ordering based on determination of provider/site needs:
  - Education
  - Equipment change
  - Demonstration of improved immunization practices
  - And documentation of these measures

# Identification of Fraud and/or Abuse

- **Fraud** is defined in Module 10 of the VFC Operations Guide as:

“an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person.”



# Definition of Abuse

- **Abuse** is defined in Module 10 of the VFC Operations Guide as:  
  
“provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care...”

# Examples of Fraud and Abuse

- Providing VFC vaccine to non VFC-eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum regional charge (\$14.47) for administration of a VFC vaccine to a federally vaccine-eligible child
- Not providing VFC-eligible children VFC vaccine because of parents' inability to pay for the administration fee
- Not implementing provider enrollment requirements of the VFC program

# Examples of Fraud and Abuse

- Failing to screen patients for VFC eligibility at every visit
- Failing to maintain VFC records for a minimum of three (3) years or comply with other requirements of the VFC program
- Failing to fully account for VFC vaccine through required monthly reporting of doses administered, doses wasted, and inventory on hand;
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine or reporting vaccine usage in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC doses
- Wastage of VFC vaccine due to negligence

# Reimbursement to the VFC Program

- Fraud and Abuse Coordinator will review incidents surrounding the situation
- Provider may be required to reimburse for mismanaged vaccine

# Referral to Outside Agencies

- Failure to comply with program requirements may result in referral to appropriate law enforcement agency for further action
  - Medicaid Fraud Control Unit (MFCU) of the Attorney General
  - Office of the Inspector General (OIG)
- Laws enforced may be relevant to consumer protection and healthcare professional licensing

# **Provider Responsibilities**

Best Practices to Maintain  
Your Immunization Program's Integrity!

# How to Ensure Integrity

1. Accurate and up-to-date VFC Provider Profiles
  - Give VFC vaccine to VFC eligible children
  - Order only what you will use
  - Use what you order
  - Vaccine In = Vaccine Out
  - Utilize CHIRP inventory management

# How to Ensure Integrity

## 2. Minimize vaccine wastage

- Do not let vaccines expire in your refrigerator or freezer
- Utilize CHIRP
- Utilize written policy for vaccine ordering and inventory management
- Best storage and handling practices
- Rotate vaccines, look at expiration dates



# How to Ensure Integrity

## 3. Best immunization Practices

- 6 rights of medication administration
  - Includes VFC eligibility screening
- Documentation and SOPs
- Utilize CHIRP

# How to Ensure Integrity

4. Immunization knowledge should be current and comprehensive.

- Immunization A to Z class
- VFC Refresher class
- CHIRP training
- CDC continuing education
- Attend the annual conference
- Specialized training



Due to high turnover, many practices need ongoing education!

# Questions?

Thank You!

How to contact the  
Immunizations Division:  
1-800-701-0704

Email: [immunize@isdh.in.gov](mailto:immunize@isdh.in.gov)

<http://www.in.gov/isdh/17094.htm>